

TO WHOM IT MAY CONCERN

CONFORMITY DECLARATION

The undersigned E.C.S. S.r.l. having its legal premises in Via Como, 71 – 23883 Brivio (LC), in the name of Mr. IVANO REDAELLI, as General Manager

DECLARES

that biological indicators BIO-CHECK 98.B2 and BIO-CHECK 98.B4 are manufactured in compliance with the following directives:

- UNI EN ISO 11138 (current edition) "Sterilization of health care products - Biological Indicators - Part 1: General requirements";
- UNI EN ISO 11138 (current edition) "Sterilization of health care products - Biological Indicators - Part 2: Biological indicators for ethylene oxide sterilization processes";
- UNI EN ISO 11138 (current edition) "Sterilization of health care products - Biological Indicators - Part 3: Biological indicators for moist heat sterilization processes";
- European pharmacopoeia (current edition), Official pharmacopoeia of the Italian Republic (current edition);
- EN ISO 11140 (current edition) "Sterilization of health care products - Chemical Indicators – Part 1: General requirements" for the parts applicable to process indicators Class 1.

We also declare that BIO-CHECK 98.B2 and 98.B4 are not medical devices and therefore they do not fall under the requirements of the European Directive 93/42/ECC and further modifications.

Brivio, August 2021

E.C.S. S.r.l.